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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,835	01/30/2002	Thomas Richardson	UMICH-11	2416

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,835	RICHARDSON ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 24-27* is/are pending in the application.

4a) Of the above claim(s) *4,13 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-12, 14-17 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's arguments with regard to the restriction requirement have not been considered because the restriction requirement was made final in the previous Action.

Claim Objections

The objection to claim 3 is withdrawn.

Claim Rejections - 35 USC § 112

The rejection of record under 35 USC 112, second paragraph is withdrawn.

The rejection of record of claims 3 and 14 under 35 USC 112, first paragraph for lack of written description is withdrawn.

Response to Arguments- 35 USC § 112

Claims 1, 2, 5-12 and 17 are maintained as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the Office Action of August 12, 2004.

1. Applicant's arguments filed February 10, 2005 have been fully considered but they are not persuasive. Applicant submits that the written description rejection appears

to be based on the breadth of the claims and that undue breadth is only the basis for a written description rejection when the claims recite subject matter broader than what is described in the original disclosure. The instant claims do encompass a scope that is broader than what is described in the specification. Applicant also submits that the instant claims are "exactly described" because of their status as original claims. This argument is not persuasive because this principle applies to a new matter rejection and the rejection is for written description. While it is correct that all originally submitted claims are considered to be part of the original disclosure and are precluded from a new matter rejection, the fact that a particular claim is an original claim does not release Applicant from the requirement that the subject matter of the claims be ~~fully~~ adequately described.

2. Applicant recites a portion of MPEP section 2163 regarding the decision *In re Wertheim* that there is a strong presumption of adequate written description being present when an application is filed and that reduction to practice can indicate possession of the invention. Applicant further argues that because a reduction to practice is present in the application the invention is adequately described. This argument is not persuasive because Applicant has shown reduction to practice of one embodiment of the claimed invention, namely use of TNFα to reduce fat tissue; this reduction to practice does not serve as an adequate disclosure of the full breadth of compounds usable in the instant claimed method which include a large number of compounds such as nucleic acids and small organic molecules to reduce tissue types ranging from hair to bone.

3. Applicant states the Office has not provided evidence to support that operability of the invention is unpredictable. However, operability of the invention is not at issue;

the rejection for lack of written description is based on inadequate description of the numerous types of compounds that can be used to reduce or eliminate numerous types of tissue that are encompassed by the claimed method. Applicant's assertions that methods of administration of drugs are known in the art and drugs that eliminate undesired tissue exist do not overcome this deficiency.

4. Applicant submits that the breadth of tissue types and possible active compounds encompassed by the claims does not support a rejection for lack of written description because these things are not Applicant's invention and describe an analogy where the method is directed to use of a syringe. These arguments are not persuasive because while Applicant is not claiming the compounds or the types of tissue, they are claiming that these compounds have an effect on different types of tissue. To follow Applicant's analogy, they are not claiming the syringe but they are claiming that using the syringe with a particular type of contents produces a specific result. It is required that the result and the contents that accomplish it be described in order to describe the invention.

Response to Arguments- 35 USC § 102

Claims 1-3, 5, 6, 9-12, 14 and 17 are maintained as rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg et al.

5. Applicant's arguments filed February 10, 2005 have been fully considered but they are not persuasive. Applicant asserts that Goldenberg et al. do not anticipate the invention because they do not disclose a method where the sustained release formulation is administered by "injection at a local area containing the undesired tissue".

Goldenberg et al. disclose that mice were injected subcutaneously in the neck. As Applicants argued in the traversal of the 112, second paragraph rejection, the term "local area" as defined in the International Dictionary of Medicine and Biology includes a region of the body. With injection into the neck, the trunk of the mouse would be a "local area". Since fat tissue is distributed throughout the body, this injection would necessarily involve injection into a local area containing the undesired tissue. Applicant further argues that the reference of Goldenberg et al. discusses overall weight loss, not loss of undesired tissue in the local area of the injection. However, it is well-known in the art that weight loss is associated with reduction of fat tissue. An overall weight loss would include reduction of fat tissue in the trunk and hence the local area as defined by Applicant.

Response to Arguments- 35 USC § 103

6. Claims 1-3, 5-12, 14 and 17 are maintained as rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. as applied to claims 1-3, 5, 6, 9-12, 14 and 17 under 35 USC 102(b) for the reasons of record set forth in the Office Action mailed August 12, 2004.

7. Claims 1-3, 5, 6, 9-12 and 14-17 are maintained as rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. in view of Hutchinson et al., Ogawa et al. or Johnson et al. for the reasons of record set forth in the Office Action mailed August 12, 2004.

8. Claims 1-3, 5, 6, 9-12, 14, 17, 24 and 25 are maintained as rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. as applied to claims 1-3, 5,

6, 9-12, 14 and 17 above, and further in view of Silvestri et al. for the reasons of record set forth in the Office Action mailed August 12, 2004.

9. Claims 1-3, 5, 6, 9-12, 14, 17 and 24-26 are maintained as rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. and Silvestri et al. as applied to claims 1-3, 5, 6, 9-12, 14, 17, 24 and 25 above, and further in view of Merwin et al. for the reasons of record set forth in the Office Action mailed August 12, 2004.

10. In traversing each of the 103 rejections, Applicant argues that Goldenberg et al. do not teach injection of a controlled release formulation at a local area containing the undesired tissue and do not suggest use of a sustained-release formulation for the purposes of reducing tissue in a local area. For each 103 rejection Applicant argues that the other cited references do not make up for the deficiencies of the Goldenberg et al. reference and thus all 103 rejections should be withdrawn. These arguments have been fully considered but are not persuasive because Goldenberg et al. do teach injection of a sustained release formula at a local area containing the undesired tissue. Goldenberg et al. teach subcutaneous injection in the neck, which makes the trunk of the animal a "local area" as per Applicant's definition of this term. Goldenberg et al. teach overall weight loss which would include reduction of fat tissue in a local area as defined by Applicant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
May 10, 2005

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